K110455

APR 29 2011

510(k) Summary

Date of Submission: December 13, 2010
Sponsor: Kimberly-Clark
Address: 1400 Holcomb Bridge Rd, Roswell, GA30076
Contact: Ann Waterhouse, RAC
Telephone: (678) 352-6719
Facsimile: (920) 225-3108

Name of Device: Kimberly-Clark, KC100 Mask
KC100 Procedure Mask, Lavender, Blue, Yellow, Green, White
KC100 Procedure Mask with visor, Lavender, Blue, Yellow, Green, White
KC100 Procedure Mask with fog-free strip, Lavender, Blue, Yellow, Green, White
KC100 Surgical Mask, Lavender, Blue, Yellow, Green, White
KC100 Surgical Mask with visor, Lavender, Blue, Yellow, Green, White
KC100 Surgical Mask with fog-free strip, Lavender, Blue, Yellow, Green, White

Common Name/Classification Name: Mask, Surgical

Classification: Class II

Product Code: FXX

Regulation Number: 878.4040

Panel: General & Plastic Surgery

Indication for Use Statement:

The Kimberly-Clark KC100 Procedure Mask(s) is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The Kimberly-Clark KC100 Procedure Mask(s) is a single use, disposable devices, provided non-sterile.

Device Description:

The Kimberly-Clark KC100 Procedure Mask(s) is a three layer mask, constructed of nonwoven polyester blends and polypropylene materials. Bindings are nonwoven polyester. The mask is provided with earloops or ties in either knitted polyester/lycra or nonwoven polyester. A malleable nosepiece is placed within the bindings for comfort and individualized fit around the wearer's nose and may or may not contain a fog free strip. Kimberly-Clark KC100 Procedure Mask(s)

will be provided in a variety of colors, with and without a protective visor. Kimberly-Clark KC100 Procedure Mask(s) is a single use, disposable device, provided non-sterile.

Comparison to Predicate Devices:

Please reference section 11, substantial equivalence.

Predicate Device:
K082258 Crosstex Isolite, Isofluid, Ultra Fluid Resistant and Procedural Face Masks

The following tests were conducted in support of ASTM 2100 labeling:

Standard	Title
Mil- M369454C	Military Specifications: Surgical Mask, disposable 1992
ASTM F2101-07	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol, *Staphylococcus Aureus*
PSC CS-191- 53	Flammability Test Method (16 CFR 1610) for Flammability of Clothing Textiles
ASTM F2299	Standard Test Method for Evaluating the Initial Efficiency of Materials Used in Medical Masks to Penetration of Particulates Using Latex Spheres
ISO 10993	Standards for evaluating the biocompatibility of a medical device
F 1862	Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood

All testing conducted on the Kimberly-Clark KC100 Procedure Mask(s) met acceptance criteria.

Conclusions:
The Kimberly-Clark KC100 Procedure Mask(s) have the same or similar intended use and technological characteristics as the predicate devices. Bench testing demonstrates the safety and efficacy of the Face Mask to consensus standards and other relevant standards. The Kimberly-Clark KC100 Procedure Mask(s) does not raise any new questions concerning safety and effectiveness. The Kimberly-Clark KC100 Procedure Mask(s) is comparable to the predicate device cited in terms of materials of composition, design, performance, and intended use. The Kimberly-Clark KC100 Procedure Mask(s) is substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 2 9 2011

Kimberly-Clark Corporation
C/O Mr. Casey Conry
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
Melville, New York 11747

Re: K110455
Trade/Device Name: Kimberly-Clark K-C100 Face Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: April 15, 2011
Received:. April 18, 2011

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

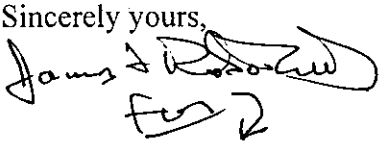
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110455

Device Name:
Kimberly-Clark KC100 Face Masks

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use ___X____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for EFC
(Division Sign-Off) 4/29/2011
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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